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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/815,727

04/02/2004

John D. Brennan

571-933

9476

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7590

03/27/2007

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EXAMINER

JUNG, UNSU

ART UNIT

PAPER NUMBER

1641

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

03/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/815,727

Applicant(s)

BRENNAN ET AL.

Examiner

Unsu Jung

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-25 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 3-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 14 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/12/07.
4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 3/14/07.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicants' amendment to claim 1 in the reply filed on January 12, 2007 have been acknowledged and entered.
2. Claims 1 and 3-25 are pending and are under consideration for their merits.

Information Disclosure Statement

3. The information disclosure statement filed on January 12, 2007 has been considered.

Rejections Withdrawn

4. Applicant's arguments, see pp17-18, filed January 12, 2007, with respect to the rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 16, 37, 38, 39, 41, 42, 47, 49, and 51 of copending Application No. 10/814,123 in view of Stowell et al. (U.S. Patent No. 6,284,163, Sep. 4, 2001) have been fully considered and are persuasive. The rejection of claims 1 and 3-25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 16, 37, 38, 39, 41, 42, 47, 49, and 51 of copending Application No. 10/814,123 in view of Stowell et al. has been withdrawn in light of the terminal disclaimer in the reply filed on January 12, 2007.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-9, 11 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (*Chem. Mater.*, Web Release Date of July 4, 2001, Vol. 13, pp3404-3421) in view of Gill et al. (*J. Am. Chem. Soc.*, 1998, Vol. 120, pp8587-8598) and Stowell et al. (U.S. Patent No. 6,284,163, Sep. 4, 2001).

Gill teaches a method of immobilizing membrane-associated molecules in silica matrixes comprising combining biomolecular structures (p3405, *General Considerations for the Encapsulation of Biomolecular Structures*), with a protein- and membrane-compatible sol-gel precursor under conditions to allow a gel to form (pp3404, Abstract), wherein the protein- and membrane-compatible sol-gel precursor is an organic polyol silane (alkoxy-silanes mixed with an organic polyol such as glycerol, pp3406-8, *The Essentials of Sol-Gel Nano-bioencapsulation* and p3407, Figure 1). Sol-gel bioencapsulation appears generic and a remarkably diverse range of enzymes, noncatalytic proteins, DNA, RNA, organelles, and living cells have been successfully encapsulated in their viable state (p3416, right column, *The Future for Sol-Gel Bioencapsulation*). Biomolecules encapsulated in sol-gel polymers are protected from biological degradation and are often considerably stabilized to chemical thermal inactivation (p3416, right column, *The Future for Sol-Gel Bioencapsulation*). However, Gill fails to teach a method, wherein the biomolecular structure is a liposome-assembly comprising a membrane-associated molecule.

With respect to the limitation of "organic polyol silane that is prepared under conditions to avoid hydrolysis and polycondensation," MPEP states that the lack of

physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Gill et al. teaches that poly(glycerol silicate) (PGS, organic polyol silane) is a protein- and membrane-compatible sol-gel precursor as efficient confinement of proteins and cells is achieved using PGS (Abstract).

Stowell et al. teaches a method of immobilizing membrane-associated molecules in silica matrixes comprising combining a liposome-assembly, which includes the membrane associated molecule (column 3, lines 59-64), with a protein- and membrane-compatible sol-gel precursor under conditions to allow a gel to form (column 3, lines 18-30). Lipid membranes and vesicles (liposomes) mimic the biological cell structure (column 1, lines 25-26). Due to its self-assembled uniform structure and resultant physicochemical properties, they have gained more research attention and application in a variety of fields (column 1, lines 26-28). However, lipid membranes and vesicles

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are fragile metastable systems (column 1, lines 28-29). The compositions of Stowell et al. are expected to have enhanced thermal and mechanical stability compared to conventional phospholipid vesicles and phospholipid lipid bilayer membranes (column 2, lines 49-52). Moreover, these compositions find application in ion specific filtration and desalination, and as detections biosensors, biocatalysts, high performance materials, optical, and diagnostic devices.

Kondo et al. teaches that silane coupling agent (in the absence of water, which would read on the conditions to avoid hydrolysis and polycondensation of the precursor) or its hydrolysis product or hydrolysis condensation product can function as a coupling (linking) agent (see entire document, particularly (column 2, lines 32-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ a liposome-assembly of Stowell et al. comprising membrane associated molecule in the method of Gill in order to immobilize membrane-associated molecules in silica matrixes. The advantage of using thermally and mechanically stable liposome-assembly of Stowell et al. for application in ion specific filtration and desalination, and as detections biosensors, biocatalysts, high performance materials, optical and diagnostic devices provides the motivation to combine the teachings of Gill and Stowell et al. with a reasonable expectation of success as Gill et al. teaches that PGS is compatible with protein and membrane in an encapsulation process. With respect to the limitation of "sol-gel precursor is an organic polyol silane that is prepared under conditions to avoid hydrolysis and polycondensation of the precursor"

With respect to claims 5 and 6, Gill fails to teach a method, wherein the organic polyol silane precursor is diglycerylsilane (DGS). According to the current specification, DGS is prepared by a method disclosed in the Provisional Application No. 60/384,084 (p30, lines 1-2), which discloses that DGS is prepared by mixing of alkoxysilane with organic polyol such as glycerol (pp9-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to recognize that the method of Gill, which involves mixing of alkoxysilane with glycerol would result in DGS.

With respect to claims 7 and 8, Gill teaches that entrapped photoactive proteins such as bacteriorhodopsin can be used in solid state optical devices and transducers (p3415, right column, lines 4-6). Gill further discloses a method of immobilizing membrane-associated molecule such as bacteriorhodopsin in silica matrix (p3415, Table 4). However, Gill teaches a method of encapsulation of bacteriorhodopsin using trimethoxysilane (TMOS), which is not an organic polyol silane precursor. Although Gill fails to specifically teach a method to encapsulate bacteriorhodopsin with an organic polyol silane, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of immobilizing membrane-associated molecule using organic polyol silane precursor as taught by Gill with a bacteriorhodopsin as a membrane-associated molecule in order to use the photoactive protein such as bacteriorhodopsin as an optical device and transducer.

With respect to claim 11, Gill teaches a method comprising the steps of (p3406 and 3408):

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(i) combining an aqueous solution of the protein and membrane-compatible, sol gel precursor with an aqueous solution of a liposome assembly comprising the membrane-associated molecule;

(ii) adjusting the pH of the combination of (i) so that it is in the range of about 4-11.5;

(iii) shaping the combination into a desired shape;

(iv) allowing the combination to gel;

(v) aging and partially drying the gel.

With respect to claim 14, Gill teaches a method of combining the biological structures and sol-gel precursor are combined in the presence of an indicator molecule and/or in the presence of one or more ligands for the biological structures (p3415, column 1, lines 1-5).

With respect to claims 15-19, Gill teaches a method of combining the biological structures and sol-gel precursor in the presence of one or more additives such as polyethylene glycol (p3407, Figure 1).

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (*Chem. Mater.*, Web Release Date of July 4, 2001, Vol. 13, pp3404-3421) in view of Gill et al. (*J. Am. Chem. Soc.*, 1998, Vol. 120, pp8587-8598) and Stowell et al. (U.S. Patent No. 6,284,163, Sep. 4, 2001) as applied to claim 9 above, and further in view of Madden (U.S. Patent No. 4,963,297, Oct. 16, 1990).

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Gill in view of Gill et al. and Stowell et al. teaches a method of immobilizing membrane-associated molecules in silica matrixes as discussed above. However, Gill in view of Gill et al. and Stowell et al. fails to teach the use of lipid comprising 1,2-dioleoyl-sn-glycerol-3-phosphocholine (DOPC) in liposome assembly.

Madden teaches a method of forming a vesicles (liposome assembly) without harsh treatments (column 2, lines 63-68). Method of Madden employs a variety of amphiphiles including DOPC (columns 7 and 8, Example 6). Further, the characteristic bilayer instability of the systems would be expected to enhance insertion of membrane proteins or peptides (column 3, lines 1-11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ a method of forming a liposome assembly using DOPC as taught by Madden in the method of Gill in view of Gill et al. and Stowell et al. in order to form liposome assembly without harsh treatments and enhance insertion of membrane proteins and peptides. The advantage of forming liposome assembly without harsh treatments provides the motivation to combine the teachings of Gill in view of Gill et al. and Stowell et al. and Madden with a reasonable expectation of success as the method of Madden would enhance insertion of membrane proteins or peptides and the inserted proteins or peptides would not be exposed to harsh treatments that may affect bioactivity of the membrane proteins or peptides.

10. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (*Chem. Mater.*, Web Release Date of July 4, 2001, Vol. 13, pp3404-3421) in

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view of Gill et al. (*J. Am. Chem. Soc.*, 1998, Vol. 120, pp8587-8598) and Stowell et al. (U.S. Patent No. 6,284,163, Sep. 4, 2001) as applied to claims 1 and 11 above, and further in view Lapidot et al. (U.S. PG Pub. No. US 2002/0064541 A1, Filed Oct April 21, 2000) and Smith et al. (*J. Am. Chem. Soc.*, Published on Web Mar. 28, 2002, Vol. 124, pp4247-4252).

Gill t in view of Gill et al. and Stowell et al. teaches a method of immobilizing membrane-associated molecules in silica matrixes as discussed above. However, Gill in view of Gill et al. and Stowell et al. fails to teach the use of aqueous buffer, comprising about 5% to about 50% (v/v) of glycerol.

Lapidot et al. teaches that the disintegration of microcapsules prepared by sol-gel process is effected by drying (p9, paragraph [0154]). The drying of the microcapsules is effected by the evaporation of water, which leaves the microcapsules exposed to the environment and thus triggers their disintegration (p9, paragraph [0155]). Additives that are capable of maintaining humidity and moisture can be added during the sol-gel process to control the surface nature of the sol-gel matrix (p9, paragraph [0156]). Examples of humectants include glycerol (p10, paragraph [0174]).

Smith et al. teaches a method of encapsulating an enzyme using a sol-gel technique (Abstract). During a gelation process, phosphate buffer comprising 10% glycerol was used during the wash step in order to remove the ethanol produced in the gelation reaction and during the aging and drying steps (p4249, left column, *Casting of Sol-Gel Monoliths*).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Gill in view of Gill et al. and Stowell et al. with a use of humectant such as glycerol in a buffer solution as taught by Smith et al. to use during the drying process as taught by Lapidot et al. in order to control the surface nature of the sol-gel matrix and remove ethanol produced during gelation reaction and during the aging and drying steps with a reasonable expectation of success.

11. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (*Chem. Mater.*, Web Release Date of July 4, 2001, Vol. 13, pp3404-3421) in view of Gill et al. (*J. Am. Chem. Soc.*, 1998, Vol. 120, pp8587-8598) and Stowell et al. (U.S. Patent No. 6,284,163, Sep. 4, 2001) as applied to claims 1 and 15-19 above, and further in view Keeling-Tucker et al. (*Chem. Mater.*, Published on Web July 31, 2001, Vol. 13, pp3331-3350).

Gill in view of Gill et al. and Stowell et al. teaches a method of immobilizing membrane-associated molecules in silica matrixes as discussed above. However, Gill in view of Gill et al. and Stowell et al. fails to teach the use of polyethylene oxide (PEO), PEO-NH₂, and poly NIPAM.

Keeling-Tucker et al. teaches a method of incorporating hydrophilic polymers within silicate materials with the silica sol (p3339, Hydrophilic Polymers, column 1, lines 1-5). The development of Class I materials generally involves the dispersion of hydrophobic, hydrophilic, or charged polymers or surfactants into sol-gel precursor

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materials during the hydrolysis step (p3338, *B. Materials with Dispersed Organic Additives (Class I Materials)*, column 2, lines 2-6). Such materials can either interact with silica, thus modifying the properties of the solvent-silica interface, or can segregate into independent phases, resulting in unique structures such as interpenetrating polymer networks (p3338, *B. Materials with Dispersed Organic Additives (Class I Materials)*, column 2, lines 6-11). The additive, PEO, was able to organize by hydrophobic interactions to provide a relatively large volume fraction of the organic subphase (p3340, column 2, paragraph 4, line 11-p3341, column 1, paragraph 1, line 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Gill in view of Gill et al. and Stowell et al. with the use of an additive, PEO, in order to provide segregation into independent phases prior to gelation.

12. Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (*Chem. Mater.*, Web Release Date of July 4, 2001, Vol. 13, pp3404-3421) in view of Gill et al. (*J. Am. Chem. Soc.*, 1998, Vol. 120, pp8587-8598) and Stowell et al. (U.S. Patent No. 6,284,163, Sep. 4, 2001) as applied to claims 1 and 15-19 above, and further in view of Leung et al. (Patent No. 6,204,202, Filed Apr. 14, 1999).

Gill in view of Gill et al. and Stowell et al. teaches a method of immobilizing membrane-associated molecules in silica matrixes as discussed above. However, Gill

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in view of Gill et al. and Stowell et al. fails to teach the use of polyethylene oxide (PEO), PEO-NH₂, and poly NIPAM.

Leung et al. teaches a method for making silica nanoporous films (such as sol-gel) of sufficient mechanical strength that are also optimized to have a desirably low and stable dielectric constant, without the need for further processing to make the film hydrophobic (column 3, lines 19-26) by mixing a non-volatile thermally degradable polymer with an organic and/or inorganic silicon-based material (column 2, lines 44-58 and column 3, lines 34-36). A useful nanoporous material must meet a number of criteria, including having a dielectric constant falling within the required value range, having a suitable thickness, having an ability of effectively fill gaps, and having an effective degree of hydrophobicity (column 2, lines 60-66). If the material is not strong enough, despite achieving the other requirements, the pore structure may collapse, resulting in high material density, and therefore an undesirably high dielectric constant.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Gill in view of Gill et al. and Stowell et al. with an additive (thermally degrading polymer such as PEO having a molecular weight ranging from about 200 to 2,000,000 Daltons, column 4, lines 16-22) as taught by Leung et al. in order to make silica nanoporous films (such as sol-gel) of sufficient mechanical strength that are also optimized to have a desirably low and stable dielectric constant, without the need for further processing to make the film hydrophobic with a reasonable expectation of success.

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13. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (*Chem. Mater.*, Web Release Date of July 4, 2001, Vol. 13, pp3404-3421) in view of Gill et al. (*J. Am. Chem. Soc.*, 1998, Vol. 120, pp8587-8598) and Stowell et al. (U.S. Patent No. 6,284,163, Sep. 4, 2001) as applied to claims 1, 15, and 16 above, and further in view Delamarche et al. (*Langmuir*, Published on Web Sept. 11, 2003, Vol. 19, 8749-8758).

Gill in view of Gill et al. and Stowell et al. teaches a method of immobilizing membrane-associated molecules in silica matrixes as discussed above. However, Gill in view of Gill et al. and Stowell et al. fails to teach the use of an additive selected from compounds of Formula 5.

Delamarche et al. teaches the use of PEO silane onto a sol-gel polymer, poly(dimethylsiloxane) ink, resulting in a stable hydrophilic structure (p8755, 3. Conclusion, column 2, lines 1-6). The method of using PEO silane is simple and particularly effective when proteins are active molecules (p8755, 3. Conclusion, column 2, line 4-p8756, column 1, line 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Gill in view of Gill et al. and Stowell et al. with an additive of Formula 5 (p8751, Scheme 1, Formula 17) as taught by Delamarche et al. in order to provide a simple and effective means to construct a stable hydrophilic structure. The advantage of having a silica matrix, which is stable and hydrophilic, provides the motivation for combining the teachings of Gill in view of Gill et al. and Stowell et al. with a reasonable expectation of success.

Claims 16, 24 and 25 are not supported by the disclosure in parent application (10/712,015). Therefore, the priority date of the parent application is not applicable for the claims 16, 24, and 25 and the above reference, Delamarche et al. meets the criteria for a prior art.

Response to Arguments

14. Rejection of claims 1-9, 11 and 14-19 under 35 U.S.C. 103(a) as being unpatentable over Gill in view of Gill et al. and Stowell et al.

Applicant's arguments filed on January 12, 2007 have been fully considered but they are not persuasive in view of previously stated grounds of rejection.

Applicant's argument regarding the organic polyol silane prepared under conditions to avoid hydrolysis and polycondensation of the precursor (pp9-12) and Declaration under 37 CFR 1.132 is not found persuasive. The Declaration under 37 CFR 1.132 and Applicant's arguments are directed to comparison between organic polyol silane precursor, DGS alone without the presence of other precursors, with one or more organic polyol silane precursors of Gill and Gill et al. This comparison is irrelevant, as the feature of combining a single purified organic polyol silane precursor for gel formation is currently not claimed. Rather, independent claim 1 is directed to a method comprising a step of combining a liposome-assembly comprising the membrane-associated molecule with a protein- and membrane-compatible sol-gel precursor under conditions, which allow gel to form, wherein the protein- and membrane-compatible sol-gel precursor is an organic poly silane that is prepared under conditions to avoid hydrolysis and polycondensation of the precursor. According to the

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specification, the terms "a" and "an" denote "one or more" (p13, lines 15-16).

Therefore, the limitation of "sol-gel precursor is an organic poly silane" allows the presence of other precursors, and thus would not exclude the presence of other precursors (mixed precursors). In the method of Gill in view of Gill et al. and Stowell et al., precursor mixture, which comprises organic polyol silane as discussed in the previous Office Action dated September 14, 2006 (see item 11).

With respect to the limitation of "organic poly silane that is prepared under conditions to avoid hydrolysis and polycondensation of the precursor," currently recited invention is directed to a method of using a product, an organic poly silane, in a gel formation process. Therefore, the limitation of "organic poly silane that is prepared under conditions to avoid hydrolysis and polycondensation of the precursor" is a product-by-process limitation. With respect to the limitation of "organic polyol silane that is prepared under conditions to avoid hydrolysis and polycondensation," MPEP states that the lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established as discussed above (see item 8 above). We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of

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processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

In response to applicant's argument that the references fail to show certain features of applicant's invention (pp11), it is noted that the features upon which applicant relies (i.e., formation of macroporous and mesoporous silica) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

15. Rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Gill in view of Gill et al. and Stowell et al., and further in view of Madden

Applicant's arguments filed on January 12, 2007 have been fully considered but they are not persuasive in view of previously stated grounds of rejection and response to arguments set forth above (see item 14).

16. Rejection of claims 12 and 13 under 35 U.S.C. 103(a) as being unpatentable over Gill in view of Gill et al. and Stowell et al., and further in view Lapidot et al. and Smith et al.

Applicant's arguments filed on January 12, 2007 have been fully considered but they are not persuasive in view of previously stated grounds of rejection and response to arguments set forth above (see item 14).

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17. Rejection of claims 20 and 21 under 35 U.S.C. 103(a) as being unpatentable over Gill in view of Gill et al. and Stowell et al., and further in view Keeling-Tucker et al.

Applicant's arguments filed on January 12, 2007 have been fully considered but they are not persuasive in view of previously stated grounds of rejection and response to arguments set forth above (see item 14).

18. Rejection of claims 20-23 under 35 U.S.C. 103(a) as being unpatentable over Gill in view of Gill et al. and Stowell et al., and further in view of Leung et al.

Applicant's arguments filed on January 12, 2007 have been fully considered but they are not persuasive in view of previously stated grounds of rejection and response to arguments set forth above (see item 14).

19. Rejection of claims 24 and 25 under 35 U.S.C. 103(a) as being unpatentable over Gill in view of Gill et al. and Stowell et al., and further in view Delamarche et al.

Applicant's arguments filed on January 12, 2007 have been fully considered but they are not persuasive in view of previously stated grounds of rejection and response to arguments set forth above (see item 14).

Conclusion

20. No claim is allowed.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Unsu Jung, Ph.D.
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